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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,181	09/15/2003	Steven Z. Wu	50623.334	1431

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,181	WU ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,30-32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,30-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114 and the Information Disclosure Statement (IDS), all filed 01/14/09 is acknowledged.

Claims 25, 30-32 and 34 are pending in this application. Claims 25, 30-32 and 34 were previously allowed (Notice of Allowability - filed 10/14/08). Claims 25, 30-32 and 34 are herein rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 14 January 2009 has been entered.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/14/09 was filed after the mailing date of the Notice of Allowance on 10/14/08. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25, 30-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter *et al.* (hereinafter "Hunter") (U.S. Pat. No. 5,886,026).

Hunter ('026) teaches methods for treating angiogenic-dependent diseases and compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions and methods for utilizing these stents and compositions (see column 1, lines 15-20); (col.3, line 42 - col. 5, line 43). Methods for the preparation of drug-loaded microspheres, films and pastes are also disclosed (see Examples).

The anti-angiogenic compositions may be fashioned in the form of microspheres of any size ranging from 50 nm to 500 μm (col. 17, lines 31-44). The compositions may also be prepared in paste or gel forms or as films (col. 17, line 45 - col. 18, line 10); (col. 37, lines 33-45). The anti-angiogenic compositions may be administered in combination with

pharmaceutically or physiologically acceptable carriers, excipients or diluents (col. 37, lines 46-59).

Suitable polymeric carriers taught include poly(D,L-lactic acid), poly(glycolic acid), polycaprolactone, gelatin, starch, cellulose and polysaccharides for example and blends thereof (col. 16, lines 36-61). The anti-angiogenic compositions comprise a variety of active compounds in addition to the anti-angiogenic factors and polymeric carriers. Suitable active compounds are disclosed at column 15, lines 16-40).

The stents may be coated with the anti-angiogenic compositions or anti-angiogenic factors in a variety of ways, such as: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film or by dipping the stent into a polymer/drug solution), (b) by coating the stent with a substance such as a hydrogel which will absorb the anti-angiogenic composition or anti-angiogenic factor; (c) by interweaving the anti-angiogenic composition coated thread (or the polymer itself formed into a thread) into the stent structure, (d) by inserting the stent into a sleeve or mesh which is comprised of or coated with an anti-angiogenic composition or (e) constructing the stent itself with an anti-angiogenic composition (col. 22, lines 45-66).

The Examples at columns 42 onwards demonstrate various methods for the preparation of the anti-angiogenic compositions. For instance, Example 3 at column 42 demonstrates methods for the encapsulation of suramin whereby a polymer mixture is combined with the active agent (suramin) and solvent or reagent - dichloromethane (DCM). The process yields microspheres, wherein the polymer (PVA) encapsulates the active agent – suramin. Similarly, Example 4 at columns 42-43 demonstrates a procedure for the encapsulation of paclitaxel.

Example 8 at columns 45-47 outlines the manufacture of microspheres. Example 9 at columns 47-48 presents a process for the manufacture of a stent coating, wherein a sufficient quantity of polymer and DCM are added in a vial and mixed by hand in order to dissolve the polymer. An appropriate amount of paclitaxel is added to the solution and dissolved by hand shaking. The stent is coated using a horizontal spraying technique, whereby the polymer and drug are deposited on the stent.

Procedures for producing a film are discussed at columns 51-52. The films may be made by for example, casting and spraying. In the casting technique, polymer is either melted and poured into a shape or dissolved in DCM and poured into a shape. The polymer then either solidifies as it cools or solidifies as the solvent evaporates. In the spraying technique, the polymer is dissolved in solvent and sprayed onto glass, as the solvent evaporates the polymer solidifies on the glass. Repeated spraying enables a buildup of polymer into a film that can be peeled from the glass (col. 51, lines 55-63).

Also see Example 14 at columns 60-61, which demonstrates thermopastes made up of polymer (PCL containing MePEG) loaded with paclitaxel.

Procedures for producing a nanopaste are discussed at columns 52-53. The nanopaste is a suspension of microspheres suspended in a hydrophilic gel. The gel or paste can be smeared over tissue as a method of located drug-loaded microspheres close to the target tissue.

Example 11 at columns 53-57 demonstrate controlled delivery of paclitaxel from microspheres composed of a blend of biodegradable poly(D,L-lactic acid) (PLA) polymer and non-degradable ethylene-vinyl acetate (EVA) copolymer. The microspheres are prepared by a solvent evaporation method.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Hunter. Hunter teaches methods for the preparation of drug-loaded microspheres, which are provided as a coating onto a stent, whereby the drug (i.e., paclitaxel) is dissolved in a polymer solution containing a polymer and solvent (DCM), and wherein the solvent is evaporated to yield microspheres. Hunter teaches that the compositions can be in suitable forms, such as, for example, a paste, as in the form of a suspension wherein the microspheres are suspended in a hydrophilic gel, and thereafter the gel or paste can be smeared over tissue. Hunter also discloses compositions in the form of a film, whereby polymer is dissolved in a solvent, the solvent then evaporates and the polymer solidifies to form a film that can subsequently be peeled. The methods of Hunter are useful and effective for the treatment of angiogenic-dependent diseases and thus would include restenosis, as is instantly claimed.

Conclusion

- No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

March 20, 2009